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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,693	11/07/2000	Se-Jin Lee	JHU 1120-15	2065

28213 7590 01/08/2007  
DLA PIPER US LLP  
4365 EXECUTIVE DRIVE  
SUITE 1100  
SAN DIEGO, CA 92121-2133

EXAMINER
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ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1647

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/08/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

09/708,693

Applicant(s)

LEE ET AL.

Examiner

Marianne P. Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 9-11, 15, 19, 22, 26-29, 31-33, 37 and 39-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26 and 41 is/are allowed.
- 6) ☒ Claim(s) 1, 9-11, 15, 19, 22, 27-29, 31-33, 37, 39-40, 42-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicant's arguments filed 10/23/06 have been fully considered but they are not persuasive.

Claims 1, 9-11, 15, 19, 22, 26-29, 31-33, 37, 39-43 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### *Double Patenting*

The terminal disclaimer filed on 10/23/06 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent Nos. 5,827,733; 6,500,664; and 6,465,239 as well as copending Application No. 10/997,809 has been reviewed and is accepted. The terminal disclaimer has been recorded.

#### *Claim Rejections - 35 USC § 102*

Claims 1, 9-11, 15, 19, 22, 27-29, 31-33, 37, 39-40, and 42-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Barker et al. (U.S. Patent No. 6,369,201 B1).

This rejection is maintained for reasons of record.

Particular embodiments embraced by claim 1 are substantially purified peptides consisting of about amino acids 1-20 of SEQ ID NOS: 2, 4, 6, 8, 10, 12, 14, 16, 18, or 20 (the promyostatin signal peptide domain). These concepts are not disclosed by parent application 09/124,180.

Particular embodiments embraced by claims 33 and 37 are substantially purified peptides consisting of amino acids 20-262 of SEQ ID NOS: 2, 8, 10, 12, 14, 16, 18, or 20 or consisting of

about amino acids 20-263 of SEQ ID NOS: 4 or 6 (the promyostatin prodomain). These concepts are not disclosed by parent application 09/124,180.

Particular embodiments embraced by claims 19, 22, and 42-43 are substantially purified peptides consisting of about amino acids 268-375 of SEQ ID NOS: 4 or 6 or consisting of amino acids 267-374 of SEQ ID NOS: 2, 8, 10, 12, 14, 16, 18, or 20, (the promyostatin myostatin domain). These concepts are not disclosed by parent application 09/124,180, particularly with the newly introduced activity limitation.

The parent application does not disclose nor contemplate as the invention a polynucleotide encoding a peptide limited to the promyostatin signal peptide domain, promyostatin prodomain or promyostatin myostatin domain having the newly introduced activity limitations as set forth in the claims. The claims embrace these smaller domains and are not limited to the full length polypeptides. Should applicant continue to traverse, they are invited to point to the page and line number of parent application 09/124,180 setting forth these concepts. Page 44 does not disclose nor contemplate isolated polynucleotides encoding these smaller portions of the polypeptide as being the intended invention.

As such, benefit to the filing date of parent application 09/124,180 is denied for all claims. The effective filing date for these claims is considered to be 27 July 2000.

Barker et al. is valid prior art against the instant claims as this application was filed on 18 February 1999.

Barker et al. discloses the full length sequences for human, murine, rat, chicken, baboon, bovine, porcine, ovine, turkey, and zebrafish promyostatin polypeptides. Barker's SEQ ID NOS:

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29, 27, 28, and 30 corresponding directly to instant SEQ ID NOS: 4, 6, 2, and 10, respectively. Barker's SEQ ID NOS: 31-34 and 36 have a conservative substitution in a single position with respect to instant SEQ ID NOS: 12, 14, 16, 8, and 20, respectively. Barker's SEQ ID NO: 35 has two mismatches to instant SEQ ID NO: 18. Particular fragments of these polypeptides are also disclosed. See at least Figure 1A-1D and column 3, lines 25-45. Note that none of the mismatches occurs in the promyostatin myostatin domain and only one mismatch (for SEQ ID NO: 18) occurs in the promyostatin signal peptide domain. However, as the mismatch in SEQ ID NO: 18 is at amino acid three, this is considered to be within the claim limitation of "about 1-20." Polynucleotides encoding the proteins, expression vectors, and isolated host cells are disclosed.

This disclosure anticipates the instant claims as the claims all use "comprising" or open language and include the full length sequences as well as the fragments disclosed by Barker et al.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712.

The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Marianne P. Allen  
Primary Examiner  
Art Unit 1647

1/3/07

mpa